07 C 7162

JUDGE MANNING
MAGISTRATE JUDGE ASHMAN

# EXHIBIT A

**ID # 15689**

**IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS**
**COUNTY DEPARTMENT, LAW DIVISION**

| | | |
|---|---|---|
| THOMAS W. DURKIN, as Special Administrator Of the Estate of MARY V. DURKIN, Plaintiff, | ) | |
| Vs | ) | No. |
| BAYER CORPORATIO, BAYER PHARMACEUTICALS CORPORATION, BAYER HEALTHCARE LLC and BAYER A.G., Defendants. | ) | |

**COMPLAINT AT LAW**

**ALLEGATIONS COMMON TO ALL COUNTS**

**PARTIES**

1. THOMAS W. DURKIN, is a resident of the State of Illinois and is the Special Administrator of the Estate of MARY V. DURKIN, deceased, having been duly appointed by the Circuit Court of Cook County, Illinois, on November 20, 2007.

2. Plaintiff's decedent, MARY V. DURKIN, a resident of the State of Illinois, died on November 27, 2003.

3. Defendant BAYER CORPORATION is a corporation formed in the State of Indiana with its principal place of business located at 100 Bayer Road, Pittsburgh, Pennsylvania 15205. It is a wholly owned subsidiary of Defendant Bayer A.G. At all times material to this lawsuit, Bayer was engaged in the business of developing, manufacturing, licensing, promoting, marketing, distributing, testing, warranting and/or selling in interstate commerce and the State of Illinois, either directly or indirectly, the pharmaceutical Trasylol, also known as Aprotinin. BAYER CORPORATION may be served by delivering a copy of this complaint and summons to its agent

for service in Illinois, Illinois Corporation Service C., 801 Adlai Stevenson Drive, Springfield, IL 62703.

4. Defendant BAYER PHARMACEUTICALS CORPORATION is a wholly owned subsidiary of Defendant Bayer Corporation, incorporated in the state of Delaware, with its principal place of business located at 400 Morgan Lane, West Haven, Connecticut 06516. At all times material to this lawsuit, Bayer Pharmaceuticals Corporation was engaged in the business of developing, manufacturing, licensing, promoting, marketing, distributing, testing, warranting and/or selling in interstate commerce and the State of Connecticut, either directly or indirectly, the pharmaceutical Trasylol, also known as Aprotinin. BAYER PHARMACEUTICALS CORPORATION may be served by delivering a copy of this complaint and summons to its agent for service in Illinois, Illinois Corporation Service C., 801 Adlai Stevenson Drive, Springfield, IL 62703. On information and belief, this Defendant conducts business under the name BAYER HEALTHCARE PHARMACEUTICALS.

5. Defendant BAYER HEALTHCARE LLC is Limited Liability Company whose sole member is Defendant Bayer Corporation. On information and belief, Bayer Healthcare LLC is a citizen of both Indiana and Pennsylvania. At all times material to this lawsuit, Bayer Healthcare LLC was engaged in the business of developing, manufacturing, licensing, promoting, marketing, distributing, testing, warranting and/or selling in interstate commerce and the State of Illinois, either directly or indirectly, the pharmaceutical Trasylol, also known as Aprotinin. BAYER HEALTHCARE LLC may be served by delivering a copy of this complaint and summons to its agent for service in Illinois, Illinois Corporation Service C., 801 Adlai Stevenson Drive, Springfield, IL 62703. On information and belief, this Defendant conducts business under the name BAYER HEALTHCARE PHARMACEUTICALS.

6. Defendant, BAYER A.G., a global diversified chemical company, is a German corporation, with its principal place of business in Leverkusen, Germany. At all times relevant herein, Bayer A.G. was in the business of designing, testing, manufacturing, distributing and promoting certain pharmaceutical products, including Trasylol. Additionally, at all times relevant hereto, Bayer Corporation and Bayer A.G. shared many of the same officers and directors. Service on Bayer A.G. is being performed pursuant to the Hague Convention on service abroad. Hereinafter Bayer Corporation, Bayer Healthcare and Bayer A.G. may be collectively referred to as "Defendants."

## FACTS

7. Plaintiff hereby adopts and incorporates by reference all the above allegations and further states as follows:

### A. History of Trasylol

8. Trasylol (also known as Aprotinin injection) is a naturally occurring proteolytic enzyme inhibitor obtained from bovine lung. Aprotinin consists of 58 amino acid residues. It is a single-chain polypeptide, consisting of 6512 daltons and is cross-linked by three disulfide bridges.

9. The reactive bond site for Aprotinin is lysine – 15 – alanine – 16, and it forms reversible stoichiometric complexes.

10. Aprotinin reacts with the serine site of the enzyme.

11. Aprotinin was discovered in the 1930s when Kraut, *et al.* isolated a kallikrein inhibitor from bovine lung.

12. Aprotinin was launched as Trasylol in Germany in 1959.

13. Trasylol was approved by the FDA in 1993 and is used to control bleeding in open-heart surgeries. It is supplied as a clear, colorless, sterile isotonic solution for intravenous administration.

14. Trasylol is indicated for prophylactic use to reduce peri-operative blood loss and the need for blood transfusion in patients undergoing cardiopulmonary bypass in the course of open-heart surgical procedures.

15. Trasylol is a broad-spectrum protease inhibitor, which modulates the systemic inflammatory response associated with cardiopulmonary bypass surgery. The effects of Trasylol use in cardiopulmonary bypass surgery involve a reduction in inflammatory response, which translates into a decreased need for blood transfusions.

16. The following is the warning carried by Trasylol prior to the FDA Advisory Board Committee Meeting:

> Anaphylactic or anaphylactoid reactions are possible when Trasylol is administered. Hypersensitivity reactions are rare in patients with no prior exposure to Aprotinin. The risk of anaphylaxis is increased in patients who are re-exposed to Aprotinin-containing products. The benefit of Trasylol to patients undergoing primary CABG surgery should be weighed against the risk of anaphylaxis should a second exposure be required.

17. Trasylol inhibits pro-inflammatory cytokine release and maintains glycoprotein homeostasis.

18. According to Bayer, since its approval, an estimated 4.3 million patients have been given Trasylol.

19. Bayer estimated that Trasylol generated about $293 million in sales in 2005 alone, making it the company's 11th largest-selling drug.

20. In late 2005, Bayer forecast that Trasylol would someday generate upwards of $600 million annually.

21. On November 5, 2007, under increasing government pressure, Bayer AG said that it had halted worldwide sales of Trasylol after a Canadian clinical study found the drug could be linked to a higher risk of death than other drugs.

22. The Food and Drug Administration asked the company to stop selling the drug, used to prevent excessive bleeding during heart bypass surgery, pending detailed review of preliminary results from the Canadian study.

### B. Trasylol's Association With the Increased Risk of Renal Failure

23. On January 26, 2006, *The New England Journal of Medicine (NEJM)* published an article by Mangano, *et al.* reporting an association of Trasylol with, among other things, serious renal toxicity in patients undergoing coronary artery bypass grafting surgery. This study was an observational study of patients who received either Trasylol, one of two alternative drugs intended to decrease peripoperative bleeding (aminocaproic acid or tranexamic acid), or no specific drug treatment.

24. The FDA evaluated this study, along with other studies in the literature, and reports submitted to the FDA through the MedWatch program, to determine if labeling changes or other actions were warranted.

25. While the FDA was continuing its evaluation it provided the following recommendations to healthcare providers and patients:

> Physicians who use Trasylol should carefully monitor patients for the occurrence of toxicity, particularly to the kidneys, heart, or central nervous system and promptly report adverse event information to Bayer, the drug manufacturer, or to the FDA MedWatch program, as described at the end of this advisory.
>
> Physicians should consider limiting Trasylol use to those situations where the clinical benefit of reduced blood loss is essential to medical management of the patient and outweighs the potential risks.

### C. FDA September 21, 2006 Advisory Board Committee Meeting and the Walker Study

26. The FDA Advisory Board Committee convened on September 21, 2006 to discuss its findings regarding the safety of Trasylol and determine whether the warning on Trasylol needed to be changed.

27. After reviewing what it considered to be all of the available data on the safety of Trasylol, the 19-member advisory panel recommended to the FDA that Defendant Bayer did not need to strengthen a warning to doctors about the drug.

28. Just days later, the FDA was contacted by Alexander Walker, a professor at Harvard's School of Public Health, about a 67,000 patient-study he assisted in conducting at Bayer's request.

29. Bayer knew of this study and data and failed to disclose this data to the FDA at the September 21 Advisory Board Committee meeting. This new data from the Harvard School of Public Health study (hereinafter the "Walker Study") confirmed that Trasylol increased the risk of renal failure, among other things.

30. The Walker study, conducted at Bayer's request, examined 67,000 hospital records of patients undergoing bypass surgery. The study suggests that the patients who received Trasylol were at an increased risk for death, kidney failure, congestive heart failure, and stroke.

31. On December 15, 2006, the FDA sent an Alert to healthcare professionals advising of a change in the product label for Trasylol:

> The new labeling for Trasylol (December 2006) has a more focused indication for use, a new Warning about renal dysfunction, a revised Warning about anaphylactic reactions, and a new Contraindication. Trasylol is now indicated only for prophylactic use to reduce peri-operative blood loss and the need for blood transfusion in patients who are at *an increased risk for blood loss and blood transfusion* undergoing cardiopulmonary bypass in the course of coronary artery bypass grafting (CABG) surgery. Trasylol should be administered only in the operative setting where

> cardiopulmonary bypass can be started quickly. Trasylol should not be administered to any patient with a known or suspected exposure to Aprotinin within the past 12 months.
>
> FDA is evaluating additional recently submitted epidemiological safety study data (discussed below), in the context of all other safety and efficacy information available on Aprotinin. This review may result in other actions, including additional changes to the full prescribing information (product labeling).

32. Moreover, as of December 2006, the Defendants revised the label for Trasylol to include a specific statement in the WARNING section of the label that use of Trasylol creates an increased risk of renal dysfunction and renal failure.

### D. Specific Allegations Concerning Plaintiff's Decedent Mary V. Durkin

33. On or about October 27, 2003, Plaintiff's decedent Mary V. Durkin was administered Trasylol during the course of a cardiac surgery procedure performed at Advocate Christ Medical Center.

34. With no contributory negligence on her part, Ms. Durkin was administered Trasylol, a pharmaceutical product designed, manufactured, promoted, distributed and sold by Defendants.

35. As a direct, proximate, and legal result of the negligence, carelessness, and other wrongdoing of the Defendants, as described herein, Ms. Durkin began experiencing renal insufficiency soon after heart surgery, and subsequently went into renal failure, all of which ultimately led to her untimely death on November 23, 2003. At no time did Ms. Durkin have any knowledge that her aforementioned injuries might be related to or caused by Trasylol, nor did she have any reason to suspect that those problems might in any way be related to or caused by her physicians' perioperative use of Trasylol.

36. As a direct, proximate, and legal result of the negligence, carelessness, and other wrongdoing of the Defendants as described herein, Ms. Durkin developed kidney failure and other life threatening conditions, all of which resulted in her untimely death on November 23, 2007.

37. As a direct, proximate, and legal result of the negligence, carelessness, and other wrongdoing of the Defendants, as described herein, Ms. Durkin sustained permanent and devastating injuries and ultimately, death, all with concomitant severe pain and suffering. All of said injuries caused Mary V. Durkin extensive anxiety, distress, fear, pain, suffering, and depression, while they substantially reduced Ms. Durkin's ability to enjoy life.

38. As a direct, proximate and legal result of the negligence, carelessness and other wrongdoing of the Defendants as described herein, Thomas W. Durkin as Mary V. Durkin's surviving son and Special Administrator of her estate, incurred expenses for hospital care, medical care, nursing services, medicines, x-rays and funeral and burial expenses on behalf of Mary V. Durkin.

39. As a direct, proximate and legal result of the negligence, carelessness and other wrongdoing of the Defendants, Mary W. Durkin's capacity to earn wages was permanently destroyed.

40. As a direct, proximate and legal result of the negligence, carelessness and other wrongdoing of the Defendants, Mary W. Durkin's ability to carry out and enjoy life's activities was permanently destroyed.

## AS AND FOR A FIRST COUNT: PRODUCT LIABILITY (NEGLIGENCE, STRICT LIABILITY AND WARRANTY)

41. Plaintiff hereby adopts and incorporates by reference all the above allegations and further states as follows:

42. Defendants are liable to Plaintiff for innocent, negligent and/or willful failure to provide adequate warnings regarding the appropriate use of Trasylol to the Plaintiff's decedent and to the health care providers that prescribed Trasylol.

43. Trasylol is unreasonably dangerous, even when used for its intended purpose.

44. Defendants, as manufacturers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field, and further, Defendants had knowledge of the dangerous risks of Trasylol.

45. Plaintiff's decedent did not have the same knowledge as Defendants and Defendants provided no adequate warning to them or to the decedent's physicians about the characteristic dangers of Trasylol.

46. Defendants had a continuing duty to warn consumers and physicians, including Plaintiff's decedent, and decedent's physicians, of the risks and dangers associated with Trasylol.

47. Defendants marketed, promoted, distributed and sold an unreasonably dangerous and defective prescription drug, namely Trasylol, to health care providers who were empowered to prescribe and dispense Trasylol to consumers, including Plaintiff's decedent, without adequate warnings and Defendants misled the medical community about the risk/benefit balance of Trasylol, all of which resulted in injury to Plaintiff's decedent.

48. Despite the fact that Defendants knew or should have known that Trasylol caused unreasonable and dangerous side effects that many users would be unable to avoid by any means, they continued to promote and market Trasylol when there existed safer and more effective alternative drug products.

49. Defendants knew or should have known that consumers, and Plaintiff's decedent specifically, would foreseeably and needlessly suffer severe personal injury as a result of these Defendants' failure to warn.

50. Defendants failed to provide timely and adequate warnings to physicians, distributors, and consumers, including Plaintiff's decedent and decedent's physicians, in the following ways:

a) Failed to include adequate warnings with the medications that would alert Plaintiff's decedent and her surgeons to the dangerous risks of Trasylol;

b) Failed to provided adequate post-marketing warnings and instructions after the Defendants knew or should have known of the significant risks of, among other things, kidney failure;

c) Continued to aggressively promote Trasylol, even after it knew or should have known of the risks of injury from this drug.

51. By failing to warn Plaintiff's decedent and her physicians of the adverse health risks associated with the administration of Trasylol, Defendants breached their duty of reasonable care and safety.

52. Defendants' actions described above were performed willfully, intentionally, and with reckless disregard of the life and safety of the Plaintiff's decedent and the public.

53. As a direct and proximate result of the actions and inactions of the Defendants as set forth above, Plaintiff's decedent suffered the injuries and damages set forth in this Complaint.

54. Defendants are liable to Plaintiff for the injuries and damages due to the defective design or formulation of Trasylol.

55. At all times material to this lawsuit, Defendants manufactured Trasylol.

56. At all times material to this lawsuit, Defendants were engaged in the business of distributing and selling Trasylol.

57. Defendants sold Trasylol, which was administered to Plaintiff's decedent prior to, during, or following her heart surgery, as alleged in this Complaint.

58. The Trasylol administered to Plaintiff's decedent was defective in design or formulation in that when it left the hands of the Defendants, this drug was dangerous to the extent beyond that which could reasonably be contemplated by Plaintiff's decedent, and any benefit of this drug was far outweighed by the serious and undisclosed risks of its use when prescribed and used as the Defendants intended.

59. The Trasylol administered to Plaintiff's decedent was defective due to inadequate warning(s), inadequate public or regulatory reporting regarding the results of any testing and studies, and misleading or false promotional, medical, and scientific statements.

60. On information and belief, the Trasylol administered to Plaintiff's decedent was defective due to improper manufacture in that substantial amounts of Trasylol were contaminated with foreign matter and particulate.

61. The Trasylol administered to Plaintiff's decedent was defective at the time it was distributed by the Defendants or left their control.

62. The Trasylol administered to Plaintiff's decedent was expected to reach the user without substantial change in the condition in which it was sold.

63. The Trasylol administered to Plaintiff's decedent reached her without substantial change in the condition in which it was sold.

64. Plaintiff's decedent was a person who would reasonably be expected to use Trasylol.

65. The defects in the Trasylol administered to Plaintiff's decedent were a direct and proximate cause of the injuries and damages sustained by Plaintiff's decedent as set forth in this Complaint.

66. Defendants are liable to Plaintiff for the negligent development, study, manufacture, distribution and sale of the unreasonably dangerous product Trasylol.

67. At all times relevant to this lawsuit, Defendants owed a duty to consumers, including Plaintiff's decedent, and to ther health care providers to assess, manage, and communicate the risks, dangers, and adverse effects of Trasylol and to suspend distribution and sale of Trasylol when Defendants discovered it to be unreasonably dangerous.

68. Defendants' duties included, but were not limited to, carefully and properly designing, testing, manufacturing, licensing, packaging, promoting, advertising, selling, and/or distributing Trasylol into the stream of commerce, and providing warnings with regard to this drug.

69. Defendants negligently and carelessly breached the above-described duties to Plaintiff's decedent by committing negligent acts and/or omissions including, but not limited to, the following:

(a) Defendants failed to use ordinary care in designing, testing, and manufacturing Trasylol so as to avoid the high risk to users of unreasonable, dangerous side-effects, some of which are fatal, such as renal failure;

(b) Defendants failed to accompany Trasylol with adequate warnings that would alert doctors, consumers, and other users to the potential adverse side effects associated with the use of these drugs and the nature, severity and duration of such adverse effects;

(c) Defendants failed to conduct adequate pre-clinical testing and post-marketing surveillance to determine the safety and side effects of Trasylol;

d) Defendants failed to warn Plaintiff's decedent prior to actively encouraging the sale of Trasylol, either directly or indirectly, orally or in writing, about the possibility of becoming disabled as a result of the use of these drugs;

e) Defendants continued to promote the safety of Trasylol, while downplaying any risks, even after Defendants knew of the risk of renal failure; and

f) Defendants were otherwise careless or negligent.

70. Although Defendants knew or should have known that Trasylol caused unreasonably dangerous side effects that many users would be unable to remedy by any means, Defendants continued to market this drug to doctors for use in cardiac surgeries, despite the fact that there were safer and less expensive alternatives available.

71. Defendants knew or should have known that consumers, like Plaintiff's decedent, would suffer injury as a result of Defendants' failure to exercise ordinary care, as described above.

72. As a direct and proximate cause of Defendants' negligent acts and/or omissions, Plaintiff's decedent suffered each of the injuries and damages set forth in this Complaint.

73. Defendants are liable to Plaintiff and Plaintiff's decedent for innocent, negligent and/or willful misrepresentations regarding the safety, efficacy, and risk/benefit ratio of Trasylol to Plaintiff's decedent and to the health care providers that prescribed, recommended, ordered, and dispensed Trasylol.

74. Through their actions and omissions in advertising, promoting, reporting to the FDA, labeling, and otherwise, Defendants fraudulently, intentionally and/or negligently made public misrepresentations of material facts to, and/or concealed material facts from physicians, the FDA, and consumers like Plaintiff's decedent, concerning the character and safety of Trasylol.

75. Those public misrepresentations and omissions include, but are not limited to, those set forth in the general allegations section of this Complaint. Those misrepresentations and omissions further include, but are not limited to, the following:

a) Defendants failed to disclose that sufficient pre-clinical and clinical testing and adequate post-marketing surveillance to determine the safety and side effects of Trasylol;

b) Defendants failed to timely disclose, and/or intentionally concealed, the interim and final results of the Walker Study showing that Trasylol use dramatically increased the risk for renal failure;

c) Defendants failed to include adequate warnings with Trasylol about the potential and actual risks, and nature, scope, severity, and duration of any serious side effects of this drug, including without limitation, the risk of renal failure; and

d) Defendants concealed and continue to conceal past and present facts – including that as early as the mid-nineties Defendants were aware of and concealed their knowledge of an association between the use of Trasylol and dangerous side effects, including renal failure – from the consuming public, including Plaintiff's decedent, when it had a duty to disclose.

76. Defendants' above-described acts and/or omissions were performed willfully, intentionally, and with reckless disregard for the safety of Plaintiff and Plaintiff's decedent and the public.

77. Defendants knew or should have known that their representations were false and that Plaintiff's decedent and her physicians would rely on them. Defendants were obligated to disclose the foregoing risks, but failed to adequately and timely do so even after they were in possession of

information concerning those risks. Defendants' representations that Trasylol was safe for its intended use were false, since this drug was, in fact, dangerous to the health of Plaintiff's decedent when used to reduce perioperative bleeding in patients undergoing cardiac surgery, and there were alternative products available that were less expensive, effective and posed less risk.

80. In the alternative, Defendants failed to exercise reasonable care in ascertaining the accuracy of the information regarding the safe use of Trasylol and communicating that information to Plaintiff's decedent.

81. At the time of Defendants' fraudulent misrepresentations and active concealment, Plaintiff was unaware of the falsity of the foregoing representations and was similarly unaware that material facts concerning Trasylol had been concealed or omitted by the Defendants. In reliance upon Defendants' misrepresentations, Plaintiff's decedent's physicians were induced to and did order Trasylol to be administered during his heart surgery.

82. If Plaintiff's decedent had known the true facts concerning the risks of the use of Trasylol, in particular the risk of renal failure, she would have requested Trasylol not be used, and would have requested that her physicians order the use of one of the safer alternatives.

83. If Plaintiff's decedent's physicians had known the true facts concerning the risks of the use of Trasylol, in particular the risk of renal failure, the physicians would not have administered Trasylol during surgery and would have administered one of the safe alternatives.

84. Plaintiff's decedent's reliance and ther physicians' reliance, on Defendants' misrepresentations was justified, among other reasons, because said misrepresentations and omissions were made by individuals and entities who were in a position to know the true facts concerning Trasylol, while Plaintiff's decedent was not in a position to know the true facts, and because Defendants aggressively marketed the use of this drug and concomitantly downplayed the

risks in its use, thereby inducing Plaintiff decedent's physicians to use these drugs in lieu of other, safer alternatives. At all times relevant hereto, Defendants' corporate officers, directors and/or managing agents knew of and ratified the acts of Defendants, as alleged herein.

85. As a direct and proximate result of Plaintiff and Plaintiff's decedent's reliance, and their physicians' reliance on Defendants' misrepresentations and concealment concerning the risks and benefits of Trasylol, Plaintiff and Plaintiff's decedent suffered -- and Plaintiff Thomas W. Durkin continues to suffer from the injuries and damages as set forth in this Complaint.

86. As a direct result of Defendants' fraudulent concealment of the dangers of Trasylol, and consequently, their concealment of the fact that Plaintiff had a cause of action arising from Defendants' acts and omissions as set forth herein, Plaintiff was unable to and did not discover Trasylol was a defective product until September of 2006, when Defendants' fraudulent concealment of the risks of the use of Trasylol, in particular the risk of renal failure, was brought to the attention of the FDA. Therefore, Plaintiff's causes of action shall be deemed to accrue in September of 2006 minus any tolling provisions for Plaintiff decedent's untimely death.

87. Trasylol was designed, tested, manufactured, distributed, promoted and sold by the Defendants; and was expected to, and did, reach Plaintiff's decedent without a substantial change in its condition.

88. Defendants, through their advertising and promotional materials, expressly warranted that Trasylol was safe for the use for which it was intended, namely as a means to reduce perioperative bleeding in patients undergoing cardiac surgery.

89. Defendants breached said express warranties in that Trasylol was unsafe in light of the risk of life-threatening side effects associated with its use, including, but not limited to, renal failure.

90. Plaintiff's decedent and her physicians, relied to decedent's extreme detriment on Defendants' express warranties.

91. As a direct and proximate result of Defendants' breach of express warranties, Plaintiff's decedent 2suffered from the injuries and damages set forth in this Complaint.

91. Trasylol was designed, tested, manufactured, distributed, promoted and sold by the Defendants; and was expected to, and did, reach Plaintiff's decedent without a substantial change in its condition.

923 Defendants, through advertising and promotional materials, impliedly warranted that Trasylol was safe for the use for which it was intended, namely as a means to reduce perioperative bleeding in patients undergoing cardiac surgery.

94. Defendants breached said implied warranties in that Trasylol was unsafe in light of the risk of life-threatening side effects associated with its use, including, but not limited to, renal failure.

95. Plaintiff's decedent and her physicians relied to his detriment on Defendants' implied warranties.

96. As a direct and proximate result of Defendants' breach of implied warranties, Plaintiff's decedent suffered from the injuries and damages set forth in this Complaint.

97. Defendants are liable to Plaintiff Wholly separate and apart from the personal injuries sustained by Plaintiff's decedent, Plaintiff further suffered financial injury, as described below.

98. Defendants financed, assisted, supported and participated in the promotion and use of Trasylol in order to create and increase consumer demand for the drug and to increase the likelihood that physicians would order the use of Trasylol rather than other safer alternative treatments for their patients.

99. Defendants deliberately misrepresented the safety of Trasylol and intentionally concealed the risks attendant to use of the drug. In so doing, Defendants intended to and did affect the decisions of consumers and their health care providers to purchase, prescribe and use Trasylol despite the existence of substantially cheaper alternative drugs.

100. Defendants, while engaged in the conduct and practices identified above, committed one or more violations, including, but not limited to, the following:

a) Defendants made false and misleading representations and omissions of material facts regarding Trasylol;

b) Defendants concealed and otherwise failed to publicize the risks and injuries associated with Trasylol in order to promote sales of the drug and maximize profits; and

c) Defendants engaged in advertising and promotion of Trasylol without conducting sufficient pre-clinical and clinical testing and adequate post-marketing surveillance to determine the safety and side effects of Trasylol.

101. Defendants thereby intended to and did affect the price of Trasylol, unfairly and deceptively maintaining the price of Trasylol at an inflated level not otherwise obtainable and caused Plaintiff's decedent and the consuming public generally to pay more for the drug than was warranted or than they would otherwise have paid in the absence of Defendants' misrepresentations and concealment.

102. The above-described conduct, practices, acts and omissions were immoral, oppressive, unethical and/or unscrupulous, in violation of international treaty and law, and/or offend public policy.

103. The above-described conduct, practices, acts and omissions caused consumers permanent and substantial financial loss, which loss could not reasonably have been avoided, and

which was not outweighed by any countervailing benefit to the consuming public. Consumers in general, and Plaintiff's decedent in particular, incurred unnecessary expenses for a product that was purchased only because of the unfair, unscrupulous, oppressive and/or deceptive acts or practices of the Defendants.

104. As a consequence of Defendants' wrongful conduct, Plaintiff suffered an ascertainable financial loss: the difference between the price paid for Trasylol as a result of the Defendants' unfair trade practices and the cost of any of the substantially cheaper, and safer, drug alternatives.

105. In addition, as a consequence of Defendants' wrongful conduct, Plaintiff suffered further ascertainable financial loss: the difference between the cost of an uneventful post-operative recovery and the additional costs for medical and hospital care and post-mortem costs (funeral expenses, etc.,) incurred as a result of the many diverse and severe consequential injuries suffered by Plaintiff's Decedent as a result of the defective drug, namely Trasylol, used perioperatively. Plaintiff contends that these additional costs and expenses would not have been incurred but for Defendants' unfair trade practices and their design, manufacture, distribution and marketing of a defective, unreasonably dangerous drug, namely, Trasylol.

**AS AND FOR A SECOND COUNT: PUNITIVE DAMAGES**

106. Plaintiff is entitled to punitive damages because Defendants' actions were reckless and without regard for the public's safety and welfare. Defendants misled both the medical community and the public at large, including Plaintiff's decedent, by making false representations about and concealing pertinent information regarding Trasylol. Defendants downplayed, understated and disregarded its knowledge of the serious and permanent side effects associated with the use of

Trasylol, including renal failure and death, despite available information demonstrating the product was likely to cause serious and sometimes fatal side effects to its users.

107. The Defendants' conduct in designing, testing, manufacturing, promoting, advertising, selling, marketing, and distributing Trasylol, and in failing to warn Plaintiff, Plaintiff's decedent, Plaintiff's Decedent's physicians, and other members of the public of the dangers inherent in the use of Trasylol, which were well known to the Defendants, was attended by circumstances of fraud, malice, or willful and wanton conduct, done heedlessly and recklessly, without regard to consequences, or of the rights and safety of others, particularly Plaintiff's decedent.

108. At all times material hereto, Defendants had a duty to exercise reasonable care in the design, manufacture, testing, research and development, processing, advertising, marketing, labeling, packaging, distribution, promotion and sale of Trasylol.

109. Defendants breached their duty and were wanton and reckless in their actions, misrepresentations, and omissions toward the public generally,Plaintiff's decedent specifically, in the following ways:

a) Upon information and belief, Defendants actually knew of Trasylol's defective nature, as set forth herein, but continued to design, manufacture, market, and sell Trasylol so as to maximize sales and profits at the expense of the health and safety of the consuming public, including Plaintiff and Plaintiff's decedent, and in conscious disregard of the foreseeable harm caused by Trasylol;

b) Defendants spent millions of dollars a year researching and developing medicines and aggressively marketing Trasylol, but devoted far less attention to conducting sufficient pre-clinical testing, clinical testing and adequate post-marketing surveillance of this drug; and

c) Defendants continued to promote the safety of Trasylol, while providing no warnings at all about the risk to consumers of death, kidney failure, congestive heart failure, and stroke associated with it, even after Defendants knew of that risk from multiple studies including the Walker Study.

110. Defendants knew that Trasylol had unreasonably dangerous risks and caused serious side effects of which Plaintiff would not be aware. Defendants nevertheless advertised, marketed, distributed, and sold the medicine knowing that there were safer methods and products available.

111. Defendants' above-described actions were performed willfully, intentionally, and with reckless disregard for the rights of Plaintiff's decedent and the public.

112. One or more of the aforesaid violations by Defendants were committed by Defendants with reckless disregard for the safety of the public and of Plaintiff 's decedent as a product user.

113. One or more of the aforesaid violations by Defendants were committed by Defendants willfully and deliberately, and caused substantial financial injury to the consuming public, the Plaintiff and Plaintiff's decedent.

114. As a direct and proximate result of the wanton and reckless actions and inactions of the Defendants as set forth above, Plaintiff is entitled to punitive damages.

**WHEREFORE**, Plaintiff requests that the Court grant her the following relief against Defendants, Bayer Corporation, Bayer Healthcare, and Bayer A.G., jointly and severally, on all counts of this Complaint, including:

(A) Money Damages representing fair, just and reasonable compensation;

(B) Punitive and/or Treble Damages;

(C) Attorneys' fees

(D) Pre- and post-judgment interest as authorized by law on the judgments which enter on their behalf;

(E) Costs of suit; and

(F) Such other relief as is deemed just and appropriate.

Respectfully submitted,

**BY:** _____

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**IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS**
**COUNTY DEPARTMENT, LAW DIVISION**

THOMAS W. DURKIN, as Special Administrator Of the Estate of MARY V. DURKIN and THOMAS V. DURKIN, Individually,
Plaintiffs,

Vs

BAYER CORPORATIO, BAYER PHARMACEUTICALS CORPORATION, BAYER HEALTHCARE LLC and BAYER A.G.,
Defendants.

000009

CC J.M.

2007

No. 07L 13111

**ORDER**

THIS CAUSE having been heard on the Petition to Appoint a Special Administrator;

IT IS HEREBY ordered that the decedent's son, WILLIAM W. DURKIN is appointed Special Administrator of the estate of MARY V. DURKIN, Deceased.

ENTER:

JUDGE

ENTERED
JUDGE WILLIAM D. MADDUX-1559
NOV 20 2007
DOROTHY BROWN
CLERK OF THE CIRCUIT COURT
OF COOK COUNTY, IL
DEPUTY CLERK

DATE:

Jeffrey B. Sussman
Sussman, Selig & Ross
One E. Wacker Dr., Ste. 3650
Chicago, IL 60601
(312) 977-4000
ID #15689

**1910 - No Fee Paid**
**1919 - Fee Paid**
**JURY DEMAND** **(Rev. 1/12/01) CCG 0067**

**IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS**

Thomas W. Durkin, as Special Adm. of the Estate of Mary V. Durkin

v.

Bayer Corporation, et al.

No. 07L013111

**JURY DEMAND**

**The undersigned demands a jury trial.**

(Signature)

Atty. No.: 15689

Name: Sussman, Selig & Ross

Atty. for: Plaintiff

Address: One E. Wacker Dr., Ste. 3650

City/State/Zip: Chicago, IL 60601

Telephone: (312) 977-4000

Dated: November 19, 2007

DOROTHY BROWN, CLERK OF THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS